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Bcc: []
From: CN=Burt Shephard/OU=R10/O=USEPA/C=US
Sent: Wed 10/10/2012 4:58:39 PM
Subject: Re: Risk Assessments
[Ecological Risk Assessment Guidance for Superfund Interim Final June 1997 all in one file.pdf](#)
[Pat Rizzuto](#)
[Framework for Human Health Risk Assessment to Inform Decision Making](#)
[146 DEN A-2, 7/31/12](#)
[194 DEN A-8, 10/9/12](#)
[Dose-Response Framework](#)

This group needs to read (or re-read) the introductory sections of Chapters 7 and 8 of EPA's June 1997 Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments. Chapter 7 (Risk Characterization) is clearly described as "the final phase of the risk assessment process" and is prepared by a risk assessment team. Chapter 8 (Risk Management) explicitly states "Risk management is a distinctly different process from risk assessment" whereas the summary section of Chapter 8 clearly states "risk management decisions are the responsibility of the risk manager (the site manager), not the risk assessor".

Not sure how the EPA ecological risk assessment guidance document can be much clearer than that.

Best regards,

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"Facts are stubborn things"
- John Adams

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Cc: Chip Humphrey/R10/USEPA/US@EPA, Burt Shephard/R10/USEPA/US@EPA
Date: 10/10/2012 07:50 AM
Subject: Risk Assessments

Our friend Peter is quoted in this....See highlighted text - is this timely, or what!?

EPA's Assessors Should Answer Questions
Decisionmakers Have, Advisory Panel Says
By Pat Rizzuto

An Environmental Protection Agency strategy document should advise agency staff developing risk assessments to respond to questions from EPA program offices using the risk assessments for regulations or other risk management decisions, members of a peer review panel said Oct. 9.

The agency should make it clear, however, that decisionmakers are not supposed to tell risk assessors what conclusions their analyses should reach, said Peter deFur, chairman of the peer review panel that evaluated EPA's draft Framework for Human Health Risk Assessment to Inform Decision Making.

EPA's research office designed the document, released July 30, to guide the risk assessments that underlie ambient air quality standards, pesticide regulations, superfund cleanups, and other regulations and risk management decisions (146 DEN A-2, 7/31/12).

Risk assessors, a term that may refer to single person such as a toxicologist or a team of scientists, prepare analyses to explain the health and environmental risks a chemical or situation poses. The decision as to how to manage that risk—the decision about how much of a chemical should be removed from a superfund site—is made by one or more other agency staff who typically consider costs, feasibility, and other factors.

Each of the peer review panel members offered his or her own evaluation of EPA's draft framework. The panel is not required to reach consensus. A report summarizing each panelist's advice will be compiled and sent to the agency around the end of October, said David Bottimore, a vice president with Versar Inc., the consulting company handling logistics for EPA's peer review.

List Likely Questions?

Panel member Michael Callahan, a consultant, said the document should encourage risk assessors to answer specific questions risk managers will have.

For example, the document might list issues a risk manager is likely to raise such as whether the analysis answered questions interested parties raised and whether it explored the health implications of various decisions the risk manager could make, Callahan said. He has retired from EPA, where he was a science program manager in the agency's water, toxic substances, and research and development offices.

Nevertheless, the framework should reinforce the need for there to be a distinction between risk assessment and risk management, deFur said. DeFur is president of Environmental Stewardships Concepts, an environmental consulting company that represents community organizations.

In EPA's regions, decisionmakers, also called risk managers, sometimes tell the junior staff who conduct risk assessments which conclusions their analyses must reach, he said.

Panel member Penny Fenner-Crisp, a consultant who retired from EPA where she served as senior science adviser to the director of the Office of Pesticide Programs, said the problem of risk managers telling assessors what conclusions to reach happens not only in the regions but also at headquarters. She told the panel she would not provide specific examples.

Describe Problems

Panel member Gregory Paoli, a co-founder of the Canadian consulting firm of Risk Sciences International Inc., said that if the framework is going to have teeth, it must describe problems that prevent risk assessments from achieving their goals.

Never-ending risk assessments illustrate one type of problem, Paoli said.

There should be some place in EPA's framework that tells risk assessors to stop, he said. Continuing an assessment beyond its usefulness to help a risk manager make decisions is not helpful, he said.

During the public comment portion of the meeting, Adam Carpenter, a regulatory analyst with the American Water Works Association (AWWA), agreed with the idea that EPA's framework should include examples of problematic risk assessments practices. AWWA made similar points in comments submitted prior to the peer review meeting (194 DEN A-8, 10/9/12).

Resources to be Included in Framework

Other speakers pointed to additional resources the agency might include in its framework.

Richard Becker, senior toxicologist with the American Chemistry Council's Center for Advancing Risk Assessment Science and Policy, said a draft "Dose-Response Framework" developed by the Alliance for Risk Assessment to help formulate problems could be useful. The alliance's web-based tool provides risk assessor links to more than 30 case studies that discuss various analytical tools that could be helpful for different kinds of decisions they must make, Becker said.

The Alliance for Risk Assessment is a collaboration of organizations such as Toxicology Excellence for Risk Assessment and Noblis Inc. that provide risk assessment services.

Fred Boelter, a principal with Environ International Corp., a consulting firm, said although EPA's framework was not specifically addressing workplace situations, the industrial hygiene community has developed ways to evaluate human health risks and exposure that would be useful for the agency to include in its framework.

For example, The Synergist, the monthly magazine published by the American Industrial Hygiene Association, completed in August a four-part series examining risk assessment, Boelter said.

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